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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/879,216	06/13/2001	Robert E. Richard	12013/59001	4088

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EXAMINER	
TSOY, ELENA	

ART UNIT	PAPER NUMBER
1762	

DATE MAILED: 06/26/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/879,216	RICHARD, ROBERT E.	
	Examiner	Art Unit	
	Elena Tsoy	1762	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *28 April 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *3-6,9,10,12-15,28,29,31 and 33-36* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *3-6,9,10,12-15,28,29,31 and 33-36* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

Response to Amendment

Applicant's telephonic request for reconsideration of the finality of the rejection of the last Office action due to swearing behind a reference of Rowan is persuasive and, therefore, the finality of that action is withdrawn. All rejections have been withdrawn because they were based on the reference of Rowan.

The new action is as follows:

Claim Rejections - 35 USC § 112

1. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

2. Claims 33-36, 3-6, 10, 28, 29, 31 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Language of claim 33 is confusing because it is not clear whether the stent precoated with the **swellable** carrier coating **or** the stent with a **swollen** coating is contacted with the supercritical fluid carrying the therapeutic. For examining purposes the phrase was interpreted as the stent with a **swollen** coating is contacted with the supercritical fluid carrying the therapeutic.

Claim Rejections - 35 USC § 103

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

4. Claims 12, 14-15, 31, 33-35, 4-6, 9, 10 are rejected under 35 U.S.C. 103(a) as being unpatentable over Wu (US 6,203,551) in view of Sand (US 4,598,006).

Wu discloses a method of swell loading a stent 28 having a coating of a polymeric material with a therapeutic substance (See column 8, lines 6-15; column 9, lines 22-24). The polymeric materials susceptible to swell loading for carrying therapeutic substances are well known and practiced in the art, e.g. polyethylene or EVA (See column 8, lines 42-43). **Swell loading** is *well understood and practiced in the art.* In a conventional and well known swell loading method, the polymeric carrier is soaked with a therapeutic substance/solvent solution. A suitable solvent is capable of not only dissolving the therapeutic substance in the solvent, but causing the polymer to swell. See column 9, lines 22-40. The solution can be a non-aqueous solution. A solvent which causes the greatest amount of swelling with the *particular polymer* is most advantageously chosen (See column 9, lines 44-47). After soaking stent 28 with the solution, the stent 28 is rapidly dried causing the polymer to collapse, trapping a high concentration of the substance into the polymer's matrices (See column 9, lines 47-53).

Wu fails to teach that SCF can be used as a solvent in a swell loading process; the process comprises swelling the polymer with a swelling agent devoid of the therapeutic substance, and then contacting the polymer with SCF carrying the therapeutic substance.

Sand teaches that SCF such as compressed CO_2 (See column 3, line 24) can be used in a swell loading process for impregnating a polymer with a pharmaceutical composition (See column 3, lines 60-68), when compressed CO_2 is a good swelling agent for polymers, such as for polyethylene or EVA (See column 3, lines 55-59), and when SCF dissolves a pharmaceutical composition (See column 3, lines 1-3). The process comprises contacting the polymer article with a solution of the pharmaceutical composition in a swelling agent maintained at supercritical conditions in autoclave (claimed chamber) (See column 4, lines 3-39), causing to swell the polymer and incorporate the pharmaceutical composition (See column 3, lines 60-68), and then reducing the pressure so that the volatile swelling agent diffuses out of the thus impregnated polymer (See Abstract). The process can be carried out by directing compressed CO_2 feed line to an autoclave containing a polymer article and pumping SCF to an intermediate pressure, then directing a compressed CO_2 feed line through a small vessel which contains impregnant so that CO_2 becomes laden with the impregnant, then forcing the impregnant-laden CO_2 into the autoclave (See column 5, lines 11-24).

The Examiner Note: the intermediate pressure of compressed CO_2 would cause the polymer swell so that a pharmaceutical solution would be added to the swollen polymer.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to have used SCF such as compressed CO_2 as a solvent in Wu for therapeutic substances soluble in SCF with the expectation of providing the desired swell loading of polymer coating with the therapeutic substance because Sand teaches that SCF such as compressed CO_2 is a good swelling agent for polymers such as for polyethylene or EVA and dissolves a pharmaceutical composition, and can be used in a swell loading process for impregnating a polymer with a pharmaceutical composition, and Wu does not limit his solvent to any particular one.

It would have been also obvious to one of ordinary skill in the art at the time the invention was made to have carried out a swell loading process of Wu as described in Sand using SCF solvent and therapeutic soluble in SCF with the expectation of providing the desired therapeutic loaded polyethylene or EVA coating because Sand teaches that SCF such as compressed CO_2 can be used in a swell loading process for impregnating a polymer with a pharmaceutical composition, when SCF is a good swelling agent for polymers, such as for polyethylene or EVA, and if SCF dissolves a pharmaceutical composition.

As to claims 9, 31, the references fail to specifically teach recycling the therapeutic agent. However, Examiner notes that the method will not result in the attachment of all therapeutic agent present in the solution/dispersion. After coating, excess therapeutic agent will remain. Due to the high expense of pharmaceutical products, it is Examiner's position that one of ordinary skill in the art would recycle the excess solutions to recover the expensive pharmaceutical agents therein for a subsequent coating operation. In recovering the solution or dispersion from the coating chamber, a pump would be required to move the solution. Creating a pressure differential, using a vacuum would have been obvious to one of ordinary skill in the art desiring to move the solution from the chamber to a recycling location.

As to claim 6, It is well known that colloidal suspensions may be referred to as "colloidal solutions" because of the extremely small particle size of colloidal particles. Obviously swelled polymer would be able to incorporate the therapeutic agent from colloidal solutions because of the extremely small size of the agent.

5. Claims 12, 14-15, 31, 33-35, 4-6, 9, 10 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sand in view of Wu.

Sand is applied here for the same reasons as above. Sand fails to teach that the polyethylene or EVA polymer is a coating on a stent.

Wu is applied here for the same reasons as above.

Obviously stent coated with polyethylene or EVA polymer could be coated in Sand because the surface of polymer coated stent of Wu would be the same as in polymer article of Sand.

6. Claims 12, 14-15, 31, 33-35, 4-6, 9, 10 are rejected under 35 U.S.C. 103(a) as being unpatentable over Wu in view of Sand/Sand in view of Wu, further in view of Stack et al (US 5,527,337).

Stack et al teach that treating a polymer stent with SCF to swell the polymer and removing the SCF under reduced pressure create very small pores in the polymer which can be filled with a drug containing solution under hydrostatic pressure (See column 12, lines 4-10).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to have removed SCF from a swollen polymer coating of a stent in Wu in view of Sand/Sand in view of Wu thereby forming very small pores, and then added a solution of therapeutic in SCF under critical pressure with the expectation of providing the desired incorporation of therapeutic into the formed pores, since Stack et al teach that treating a polymer stent with SCF to swell the polymer and removing the SCF under reduced pressure create very small pores in the polymer which can be filled with a drug containing solution under hydrostatic pressure.

7. Claims 3, 9, 13, 28-29 are rejected under 35 U.S.C. 103(a) as being unpatentable over Wu in view of Sand/Sand in view of Wu/Wu in view of Sand further in view of Stack et al/Sand in view of Wu further in view of Stack et al/, and further in view of Allen et al (US 6,495,204).

Wu in view of Sand/Sand in view of Wu/Wu in view of Sand further in view of Stack et al/Sand in view of Wu further in view of Stack et al/ are applied here for the same reasons as above. Wu in view of Sand/Sand in view of Wu/Wu in view of Sand further in view of Stack et al/Sand in view of Wu further in view of Stack et al/ fails to teach that: (i) the medical device can

be coated by spray-on deposition (Claim 3) using nozzle (Claim 28); (ii) collecting residual SCF and therapeutic (Claim 9).

As to (i), Allen et al teach that typically coating with the use of SCFs involves the application of one or more modifying agent by batch soaking in an enclosed chamber or includes processes based upon spraying from a pressurized chamber through a narrow nozzle (See column 1, lines 65-67). Upon spraying of the fluid onto the substrate, the supercritical fluid carrying the coating material leaves the high pressure environment and is exposed to a normal atmospheric environment (See column 2, lines 7-15).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to have used spray-on deposition in Wu in view of Sand/Sand in view of Wu instead of a batch soaking in an enclosed chamber since Allen et al teach that coating with the use of SCFs can be typically done either by a batch soaking in an enclosed chamber or by spray-on deposition.

As to (ii), Allen et al further teach that SCF and a coating material can be removed and recycled for further use (See column 6, lines 60-62).

As to claim 29, Allen et al further teach that an injector 30 (with a nozzle) can be configured to inject the process fluids tangentially, perpendicularly, or at any other functional angle (claimed manipulating the nozzle to change the direction of the SCF flow). For example, a tangentially angled injector could be used in a chamber having two larger opposing regions, separated by a constricted medial region. Additionally, multiple injectors can be used to ensure that all surfaces of the non-equidimensional substrate can be appropriately modified. Alternatively, a perpendicular injector at close proximity to a substrate could be used to impregnate the substrate with higher pressure injections. In another embodiment, the processing chamber can utilize a treatment mixture comprised of the modifying agent and a carrier for applying the modifying agent, wherein the carrier is selected from the group consisting of supercritical fluid. See column 5, lines 48-63.

8. Claims 6, 10, 36 is rejected under 35 U.S.C. 103(a) as being unpatentable over Wu in view of Sand/Sand in view of Wu/Wu in view of Sand further in view of Stack et al/Sand in view of Wu further in view of Stack et al/, and further in view of Mehta et al (US 6,627,246).

As to claim 6, Mehta et al teach that the therapeutic agent can be may be mixed with SCF to form a true solution or may be in a suspension of particles (See column 9, lines 35-50). It is

well known that colloidal suspensions may be referred to as "colloidal solutions" because the extremely small particle size. Obviously swelled polymer would be able to incorporate the therapeutic agent from colloidal solutions because of the extremely small size of the agent.

As to claims 10, 36, Mehta et al teach that paclitaxel therapeutic agent (See column 8, line 29) is soluble in super critical carbon dioxide (See column 6, lines 65-67).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to have incorporated paclitaxel therapeutic agent in Wu in view of Sand/Sand in view of Wu since Wu in view of Sand/Sand in view of Wu teach that any therapeutic agent soluble in SCF can be loaded into a polymer, and Mehta et al teach that paclitaxel therapeutic agent soluble in super critical carbon dioxide.

Conclusion

8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Elena Tsoy whose telephone number is 571-272-1429. The examiner can normally be reached on Monday-Thursday, 9:00AM - 5:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Timothy Meeks can be reached on 571-272-1423. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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